c.) Remarks

The claims have been amended in order to recite the present invention with the specificity required by statute. No new matter has been added.

Claims 7 and 52 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. In response, this matter has been attended to by changing "a transformant" in claims 7 and 52 to read "a non-human transformant or a transformed cell" in conformity with the Examiner's kind suggestion.

Claim 4 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that the phrase "under stringent conditions" does not have a commonly accepted meaning. In response, the claims have been amended to recite the hybridization conditions set forth from page 89, line 21 to page 90, line 4.

Claims 12, 13 and 15 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that the term "collecting" is unclear. Although this rejection is without basis in fact, the claim has been amended to read as suggested by the Examiner, so as to reduce the issues.

Claim 6 is rejected because the invention appears to employ novel vectors. The Examiner states that the vectors are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. In response, regarding plasmid pBS-hFT9(S2), enclosed is a signed Deposit Declaration. Regarding plasmid pAMo-mFT9, such is well-known in the art and readily reproducable by the skilled artisan. See, e.g., J. B. C., 268, 22782 (1993) and U.S. Patent No. 5,384,249 at column 30 et seq., which corresponds to Japanese laid-open Patent

Application No. 5-336963 described at specification page 64, lines 18-19.

Claims 1-18, 24, 51-53 are rejected under 35 §USC 112, first paragraph, because the specification, while being enabling for an enzyme with SEQ ID No:1 or 2, does not reasonably provide enablement for such enzyme from any source or such enzymes in which one or more amino acids are deleted, substituted or added. In response, although such language is plainly accepted by the Patent Office[1/], such has been deleted simply in order to reduce the issues.

As to the Examiner's inquiry whether or not it would be routine to determine alpha 1,3-fucosyltransferase having the noted biological characteristic, such is taught in the specification from page 20, line 15 to page 25, line 22, from page 63, line 8 to page 69, line 19 and from page 89, line 5 to page 90, line 8.

In addition, obtaining the requisite polypeptide and DNA requires no undue experimentation for the following reasons:

(i) producing the α1,3-fucose transferase encoding genes from mouse or human cells without "trial and error" is described in the application.

(ii) expression cloning and hybridization are well-known and sufficiently described in the application.

(iii) Applicants' examples describe obtaining DNA encoding α1,3-fucose transferase mouse or human cells.

(iv) this invention is related to α1,3-fucose transferase having a novel activity and a gene encoding the transferase including allele variant represented by the sequence No. 3, 4 or 5 and SNPs gene, e.g., having high homology under the conditions of

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1/ A cursory search of the PTO database reveals 17 patents issued just from 1998 to date containing the phrase "one or more amino acids are deleted, substituted or added" in their claims. See, e.g., USP 6,139,902 and 5,909,688, etc.

claim 4 (h).

(v) glucose transferase having such activity was not publicly known before the filling date of the application, and the homology between the most analogous glucose tansferase and the transferase of the application is 35-38%.

(vi) those ordinarily skilled in the art can produce the protein of the application according to the method described in the application.

(vii) those ordinarily skilled in the art can produce the variant of α1,3-fucose transferase of the application according to the method described in the application.

(viii) the scope of the claims is entirely commensurate with the disclosure in the specification.

See In re Wands 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 1-7, 8, 9, 12, 17, 18, 24, 51, 52, 53 are rejected under 35 U.S.C §102(a) as being anticipated by Ge et al (J. Biol. Chem. Vol., 272(34):21357-21363). The Examiner states that Ge et. al. disclose an enzyme with identical properties, polynucleotide which encodes such enzyme, vectors and transformants comprising such polynucleotides and method of making such polypeptides and use it in a reaction to make reaction products. Claims 1-7, 8, 12, 17, 18, 24, 51, 52, 53 are ejected under 35U.S.C §102(b) as being anticipated by Lowe et al (J. Biol. Chem. Vol., 266(26):17467-17477). The Examiner states that Lowe et. al. disclose an enzyme with identical properties, polynucleotide which encodes such enzyme, vectors and transformants comprising such polynucleotides including a mammalian cell such as COS-1 and method of making such polypeptides and use it in a reaction to make reaction products.

This rejection is respectfully traversed. Prior to setting forth their bases for traversed, however, Applicants would like to briefly discuss the salient feature of the

present invention and, *inter alia*, its patentable nature over the prior art.

The enzyme of the application can synthesize the sugar chain having β1-4G1cNAc (Fucα1-3) structure existing in a nonreducting terminus using a sugar chain having Galβ1-4G1cNAc structure existing in a nonreducting terminus as a substrate, and at the same time, it cannot synthesize the sugar chain having NeuAC α2-3Galβ1-4G1cNAc (Fucαl-3) structure existing in a nonreducting terminus using a sugar chain having α2-3Galβ1-4G1cNAc structure existing in a nonreducting terminus as a substrate.

In contrast, human α1,3-fucose transferase (referred to human Fuc-TIV) described in Lowe et al. is the counterpart of mouse Fuc-TIV (see the abstract of Lowe and page 25048, left column lines 7-10). The substrate specificity of mouse Fuc-TIV; Ref 21 is shown at specification page 78, table 1.

As illustrated in table 1, mouse Fuc-TIV has activity to synthesize the sugar chain having NeuAc α2-3Galβ1-4G1cNAc (Fucα1-3) structure existing in a nonreducting terminus using a sugar chain NeuAc α2-3Galβ1-4G1cNA in a nonreducting terminus (α2-3-sialyl LnNT in table 1) as a substrate.

Accordingly, the human Fuc-TIV described in Lowe and Applicants' αl,3-fucose transferase are vastly different in terms of their substrate specificity. Plainly, the polypeptide of claim 1 is not taught by Lowe.[2/]

Ge et al. describe an α1,3-fucose transferase derived from *Helicobacter pylori*, and teaches that the enzyme can synthesize a sugar chain having β1-4G1cNAc (Fucα1-3) structure existing in a nonreducting terminus using a sugar chain having

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2/ In addition, since Lowe's DNA is only 39.5% or 40.2% homologous (See GenBank, accession no. NM002033, compare mFUTIX and hFUTIX with hFUTIV), such cannot hybridize under the "stringent condition" described in claim 4 (h).

Galβ1-4G1cNAc structure existing in a nonreducting terminus as a substrate. However, Ge's US Patent Publication No. 2002/0068347 describes that such *Helicobacter pylori* enzyme also synthesizes the sugar chain having NeuAc α2-3Galβ1-4G1cNAc (Fucαl-3) structure existing in a nonreducting terminus using a sugar chain having NeuAc α2-3Ga1βl-4GlcNAc structure existing in a nonreducting terminus as a substrate (see, e.g., claim 2 therein).

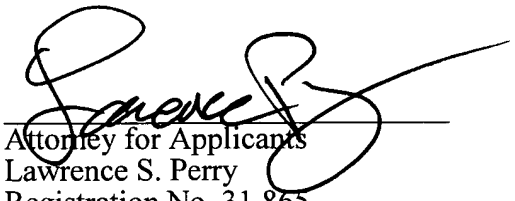
Therefore, Applicants' polypeptide is not taught by Ge.[3/]

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-75 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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3/ In addition, since Ge's DNA is only 45.1% or 45.3% homologous (See GenBank, accession no. AF008596, compare mFUTIX and hFUTIX with pylFUT), such cannot hybridize under the "stringent conditions" described in claim 4 (h).